1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

Material Name: Penicillin V Potassium Tablets

- Trade Name: Not applicable
- Synonyms: None
- Chemical Family: Penicillin
- Intended Use: Pharmaceutical product used as, antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: DANGER

Statement of Hazard:
- May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
- May cause allergic skin reaction.

Additional Hazard Information:

- **Short Term:**
  - Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe.
  - If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

- **Known Clinical Effects:**
  - May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

EU Indication of danger: Harmful

EU Hazard Symbols: 

- R42/43 - May cause sensitization by inhalation and skin contact.

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin V Potassium</td>
<td>132-98-9</td>
<td>205-086-5</td>
<td>Xn;R42/43</td>
<td>250 or 500mg***</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<td>231-545-4</td>
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<tr>
<td>Polyethylene glycol</td>
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<td>Not Listed</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
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<td>Hypromellose</td>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
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<td>Not Listed</td>
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</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turnout gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.
6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Material</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
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</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
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<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³ MAK</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>Listed</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table</td>
<td>15 mg/m³ total</td>
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<tr>
<td>Z-3 Mineral D:</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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<tr>
<td>Spain OEL - TWA</td>
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**Colloidal silicon dioxide**

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</thead>
<tbody>
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<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³ MAK</td>
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<td>Ireland OEL - TWAs</td>
<td>Listed</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
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<tr>
<td>OSHA - Final PELs - Table</td>
<td>20 mppcf TWA</td>
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<td>Z-3 Mineral D:</td>
<td></td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
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**Polyethylene glycol**

<table>
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<tr>
<th>Material</th>
<th>TWA</th>
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</thead>
<tbody>
<tr>
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<tr>
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<td>Germany (DFG) - MAK</td>
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<td>Slovenia OEL - TWA</td>
<td>Listed</td>
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</tbody>
</table>

**Titanium dioxide**

<table>
<thead>
<tr>
<th>Material</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Austria OEL - MAKs</td>
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<td>Belgium OEL - TWA</td>
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<td>Bulgaria OEL - TWA</td>
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<td>Denmark OEL - TWA</td>
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<td>Estonia OEL - TWA</td>
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<td>France OEL - TWA</td>
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<tr>
<td>Greece OEL - TWA</td>
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<td>Ireland OEL - TWAs</td>
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<td>Latvia OEL - TWA</td>
<td>Listed</td>
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<tr>
<td>Lithuania OEL - TWA</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³ total</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>Listed</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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</tbody>
</table>
Material Name: Penicillin V Potassium Tablets
Revision date: 28-Apr-2009

Manufacturer OEB Statement:
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Penicillin V Potassium
Manufacturer OEB:
OEB 2 - Sensitizer (control exposure to the range of >100μg/m³ to < 1000μg/m³, provide additional precautions to protect from skin contact)

Analytical Method:
Analytical method available for Penicillin G Potassium. Contact Pfizer Inc for further information.

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range. Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Penicillin G potassium
Mouse Oral LD50 6257 mg/kg
Rat Oral LD50 8900 mg/kg
Rabbit Oral LD50 5848 mg/kg

Povidone
Rat Oral LD50 100 g/kg

Hypermellose
Rat Oral LD50 > 10,000 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg
11. TOXICOLOGICAL INFORMATION

Magnesium stearate
- Rat  Oral  LD50  > 2000 mg/kg
- Rat  Inhalation  LC50  > 2000 mg/m³

Titanium dioxide
- Rat  Oral  LD50  > 7500 mg/kg
- Rat  Subcutaneous  LD50  50 mg/kg

Microcrystalline cellulose
- Skin Irritation  Rabbit  Non-irritating
- Eye Irritation  Rabbit  Non-irritating

Polyethylene glycol
- Eye Irritation  Rabbit  Mild
- Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Penicillin V Potassium
- 14 Day(s)  Rat  Oral  2400 mg/kg/day  NOAEL  None identified
- 14 Day(s)  Mouse  Oral  2400 mg/kg/day  NOAEL  None identified
- 13 Week(s)  Rat  Oral  750 mg/kg/day  LOEL  Gastrointestinal system
- 13 Week(s)  Mouse  Oral  250 mg/kg/day  LOEL  Gastrointestinal system

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Penicillin V Potassium
- In Vitro Bacterial Mutagenicity (Ames)  Negative
- In Vitro Cell Transformation Assay  Mouse Lymphoma  Positive with activation
- Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Positive without activation
- Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative with activation

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Penicillin V Potassium
- 2 Year(s)  Rat  Oral  1000 mg/kg/day  NOEL  Not carcinogenic
- 2 Year(s)  Mouse  Oral  1000 mg/kg/day  NOEL  Not carcinogenic

Carcinogen Status:
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone
- IARC: Group 3

Talc (non-asbestiform)
- IARC: Group 3

Colloidal silicon dioxide
- IARC: Group 3

Titanium dioxide
- IARC: Group 3 (Not Classifiable)
12. ECOLOGICAL INFORMATION

Environmental Overview: The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Penicillin G potassium

*Daphnia Magna* LC50 48 Hours > 1000 mg/L

*Nitzschia fonticola* (Diatom) LC50 630 Days 2000 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases: R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases: S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

OSHA Label: DANGER
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause allergic skin reaction.

Canada - WHMIS: Classifications
WHMIS hazard class: Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

Penicillin V Potassium
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   205-086-5

Microcrystalline cellulose
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   232-674-9

Colloidal silicon dioxide
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   231-545-4

Hypermellose
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   Standard for the Uniform Scheduling
   for Drugs and Poisons:   Schedule 4

Polyethylene glycol
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed

Titanium dioxide
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   236-675-5

Magnesium stearate
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   209-150-3

Talc (non-asbestiform)
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
   EU EINECS/ELINCS List   238-877-9

Povidone
   Inventory - United States TSCA - Sect. 8(b)   Listed
   Australia (AICS):   Listed
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R42/43 - May cause sensitization by inhalation and skin contact.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet